**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

**A. 510(k) Number:** K041049

**B. Purpose for Submission:**
New device clearance

**C. Analyte:**
Influenza Type A nucleoprotein antigens

**D. Type of Test:**
Lateral flow immunochromatographic assay

**E. Applicant:**
Binax, Inc.

**F. Proprietary and Established Names:**
BinaxNOW Influenza A & B

**G. Regulatory Information:**

1. Regulation section:
   21 CFR Part 866.3330
2. Classification:
   Antigens, CF (including CF Control), Influenza virus A, B, C
3. Product Code:
   GNX
4. Panel:
   83 Microbiology

**H. Intended Use:**

1. Intended use(s):

   The BinaxNOW® Influenza A & B Test is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal wash/aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results should be confirmed by cell culture.

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   Caution: Assay sensitivity was determined primarily using archived specimens. Users may wish to establish the sensitivity of this test on fresh samples.
2. Indication(s) for use:
   NA
3. Special condition for use statement(s):
   The device is for prescription use only
4. Special instrument Requirements:
   NA

**I. Device Description:**
The BinaxNOW® Influenza A & B Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in NP specimens. These antibodies and a control antibody are

immobilized onto a membrane support as three distinct lines and combined with other reagents/pads to construct a test strip. This test strip is mounted inside a cardboard, book-shaped hinged test device.

Swab specimens require a sample preparation step, in which the sample is eluted off the swab into elution solution, saline or transport media. Nasal wash/aspirate samples require no preparation. Sample is added to the top of the test strip and the test device is closed. Test results are interpreted at 15 minutes based on the presence or absence of pink-to-purple colored Sample Lines. The blue Control Line turns pink in a valid assay.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

FLU OIA A/B Test Kit manufactured by Thermo Biostar Inc..

2. Predicate K number(s):

K021469

3. Comparison with predicate:

Performance of the BinaxNOW® Influenza A & B Test was compared to the current NOW® Flu A Test on 306 retrospective frozen clinical samples and to the NOW® Flu B Test on 303 retrospective frozen clinical samples. All clinical samples were collected from symptomatic patients at multiple physician offices, clinics and hospitals located in the Southern, Northeastern and Midwestern regions of the United States and from one hospital in Sweden. Fifty-three percent (53%) of the population tested was male, 47% female, 64% pediatric (< 18 years) and 36% adult (≥ 18 years). Nasal wash/aspirate specimens comprised approximately 57% of the samples tested, while NP swabs represented 42%. No differences in test performance were observed based on patient age and gender or based on sample type tested.

The BinaxNOW® Influenza A & B Test was 100% sensitive and 96% specific for detection of influenza A vs. the NOW® Flu A Test and 93% sensitive and 97% specific for detection of influenza B vs. the NOW® Flu B Test.

**K. Standard/Guidance Document Referenced (if applicable):**

NA

**L. Test Principle:**

Performance of the BinaxNOW® Influenza A & B Test was compared to the current NOW® Flu A Test on 306 retrospective frozen clinical samples and to the NOW® Flu B Test on 303 retrospective frozen clinical samples. All clinical samples were collected from symptomatic patients at multiple physician offices, clinics and hospitals located in the Southern, Northeastern and Midwestern regions of the United States and from one hospital in Sweden. Fifty-three percent (53%) of the population tested was male, 47% female, 64% pediatric (< 18 years) and 36% adult (≥ 18 years). Nasal wash/aspirate specimens comprised approximately 57% of the samples tested, while NP swabs represented 42%. No differences in test performance were observed based on patient age and gender or based on sample type tested.

The BinaxNOW® Influenza A & B Test was 100% sensitive and 96% specific for detection of influenza A vs. the NOW® Flu A Test and 93% sensitive and 97% specific

for detection of influenza B vs. the NOW® Flu B Test. Test performance by virus type (A vs. B), by sample type (swab vs. wash/aspirate), and overall, including 95% confidence intervals, is detailed in the following tables.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. **Precision/Reproducibility:***

A blind study of the BinaxNOW® Influenza A & B Test was conducted at 3 separate sites using panels of blind coded specimens containing negative, low positive, and moderate positive samples. Participants tested each sample multiple times on 3 different days. There was 97% (242/250) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (3 different days), between sites (3 sites), or between operators (6 operators).

***a. Linearity/assay reportable range:***

NA

***b. Traceability, Stability, Expected values (controls, calibrators, or method):***
NA

***c. Detection limit:***

The BinaxNOW® test limit of detection (LOD), defined as the concentration of influenza virus that produces positive BinaxNOW® test results approximately 95% of the time, was identified by evaluating different concentrations of inactivated Flu A/Beijing and inactivated Flu B/Harbin in the BinaxNOW® test.

Twelve (12) different operators each interpreted 2 devices run at each concentration for a total of 24 determinations per level. The following results identify a concentration of $1.03 \times 10^2$ ng/ml as the LOD for Flu A/Beijing and $6.05 \times 10^1$ ng/ml for Flu B/Harbin.

***d. Assay cut-off:***
NA

2. Comparison studies:

***a. Method comparison with predicate device:***
See J.3 above

***b. Matrix comparison:***
NA

3. Clinical studies:

***a. Clinical sensitivity:***

Performance of the Binax NOW® Flu A and Flu B Tests was compared to cell culture on 373 prospective clinical samples collected as part of a multi-center study conducted during the 2002 Flu season at physician offices and clinics located in the Western and mid-Atlantic United States. Fifty-four percent (54%) of the population tested was male, 46% female, 90% pediatric (< 18 years) and 10% adult (≥ 18 years). Nasal wash/aspirates comprised 51% of the samples tested, while NP swabs represented 49%. No differences in performance were observed based on patient age and gender or based on sample type tested.

The Binax NOW® Flu A Test was 80% sensitive and 93% specific while the Binax NOW® Flu B Test was 65% sensitive and 97% specific when compared to cell culture. The performance of the two tests by sample type (swab vs. wash/aspirate) and overall, including 95% confidence intervals, is detailed in the following tables.

***b. Clinical specificity:***

The performance of the BinaxNOW® Influenza A & B Test was compared to cell culture and/or DFA, and to the Binax NOW® Flu A Test and the Binax NOW® Flu B Test, in a prospective study conducted in 2004 outside the US. Nasopharyngeal (NP) swab and nasal wash / aspirate specimens, collected at multiple sites from children (less than 18 years of age) and adults (18 years or older) presenting with influenza-like symptoms, were evaluated in the Binax test at a central testing lab.

Forty-seven percent (47%) of the population tested was male, 53% female, 40% pediatric (< 18 years), and 60% adult (≥ 18 years). No differences in test performance were observed based on patient age or gender. There were no invalid tests reported.

One hundred and thirteen (113) NP swab specimens and 1 wash/aspirate specimen were tested. One hundred and eight (108) of the 114 samples tested were influenza negative by culture/DFA, and 6 samples were influenza positive. When compared to culture/DFA, the BinaxNOW® Test was 75% (3/4) sensitive and 100% (110/110) specific for detection of influenza A and 50% (1/2) sensitive and 100% (112/112) specific for detection of influenza B. There was 100% agreement between the BinaxNOW® Influenza A & B Test and the individual Flu A and Flu B Tests.

BinaxNOW® A & B Test specificity by sample type versus cell culture / DFA, including 95% confidence intervals, is listed below.

c. ***Other clinical supportive data (when a and b are not applicable):***

4. Clinical cut-off:

   NA

5. Expected values/Reference range:

**Expected Values**

The prevalence of influenza varies from year to year, with outbreaks typically occurring during the fall and winter months.[1] The rate of positivity found in influenza testing is dependent on many factors including the method of specimen collection, the test method used, geographic location, and the disease prevalence in specific localities. Type A viruses are typically associated with most serious influenza epidemics, while Type B are typically milder. In a multi-center clinical study conducted by Binax in the U.S. during the 2002 influenza season, the average prevalence of influenza A (as determined by viral cell culture) was 26% in nasal wash samples and 20% in NP swab samples. The average prevalence of influenza B was 21% in nasal wash samples and 20% in NP swab samples.

**N. Conclusion:**

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.